REMARKS

Claims 2, 19 and 20 have been amended. No new matter has been added. Support for the claim amendments can be found throughout the specification. Claims 5 and 6 have been cancelled.

Claims 1-4 and 7-31 are pending in the application.

Applicants thank the Examiner for indicating that claims 26-31 are allowed and claims 15-18, and 21-24 are allowable if rewritten in independent form.

CLAIM OBJECTIONS

The Examiner has objected to claims 15-18, and 21-24 "as being dependent upon a rejected base claim." See Office Action at p. 6. The Examiner however, has indicated that those claims would be allowable if rewritten in independent form. Id. Applicants thank the Examiner for kindly indicating the allowability of the claims.

CLAIM REJECTIONS

Rejection of claims under 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 2-12, and 20 under 35 U.S.C. § 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." See Office Action at p. 2. The Examiner further states that "[t]he variable groups X^1 and X^2 are undefined" and it is "therefore impossible to determine the intended scope of these claims." Id. Claims 3-12 depend from dependent claim 2. Claims 2 and 20 have been amended to define variable groups X^1 and X^2. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of claims under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1-14, 19, 20 and 25 under 35 U.S.C. § 112, first paragraph, "because the specification, while being enabling for inhibiting sodium ion transport in an airway epithelial cell or treating lung disease using the compounds set forth in the examples in the specification, does not reasonably provide enablement for the corresponding methods of using any arbitrary oxamide linkage-containing compound." See Office Action at p. 2-3. The Examiner however, contends that no direction and "[n]o guidance is provided for the selection or use of any other compound." See Office Action at p. 4. Applicants respectfully traverse this rejection.

Applicants have discovered a method of inhibiting sodium ion transport in an airway epithelial cell that includes contacting the cell with a compound including an oxyamide linkage in an amount effective to inhibit sodium ion transport. Applicants have further discovered a method of treating lung disease in a mammal that includes administering to the mammal a compound including an oxyamide linkage in an amount effective to inhibit sodium ion transport.

To satisfy enablement under 35 U.S.C. § 112, "[a]ll that is necessary is that one skilled in the art be able to practice the *claimed* invention, given the level of knowledge and skill in the art." (emphasis added). The Examiner has acknowledged that Applicants have provided working examples "directed to the use of 5-phenyl-2,4-pentadienoic acid, 7-phenyl-2,4,6-heptrienoic acid, SAHA and trichostatin." See Office Action at p. 4. Applicants have disclosed methods of evaluating the compounds that include an oxyamide linkage of the instant invention using cystic fibrosis screening assays and bronchial epithelial cell electrolyte transport assay described in the specification at, for example, Example 4 (p. 14-16), Example 5 (p. 16-17) and Example 6 (p. 17-20).

The methods of claims 1-14, 19, 20 and 25 treat conditions that are mediated by sodium ion transport in an airway epithelial cell. A person of ordinary skill in the art would recognize the nexus between the claimed pathologies and the assays described in the specification. Thus, Applicants have informed and demonstrated to a person having ordinary skill in the art how to use the compound of formula (I) according to 35 U.S.C. § 112, first paragraph. Accordingly, the specification adequately enables the claimed method. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of claims under 35 U.S.C. § 102(b)

Hite

The Examiner has rejected claims 19, 20 and 25 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,028,629 to Hite et al. ("Hite"). See Office Action at p. 4-5. Claims 20 and 25 are dependent on independent claim 19.

The Examiner contends that "Hite discloses ... the compounds B, F and G and their *in vitro* activity as 5-lipoxygenase inhibitors. Hite further discloses ... their use as anti-asthmatic compounds." See Office Action at p. 4-5.

Applicants have further discovered a method of treating lung disease in a mammal that includes administering to the mammal a compound including an oxyamide linkage in an amount effective to inhibit sodium ion transport.

Hite describes "novel 2-substituted-N-hydroxy-N-alkyl cinnamamides which are potent selective 5-LO inhibitors and useful in the treatment of asthma and allergic diseases, inflammatory bowel disease, psoriasis, shock, adult respiratory distress syndrome (ARDS) and arthritis." See col. 2, lines 1-7 of Hite. Hite does not describe a method of treating lung disease in a mammal that includes administering to the mammal a compound including an oxyamide linkage in an amount effective to inhibit sodium ion transport. See amended claim 19.

Accordingly, independent claim 19 is not anticipated by Hite. Claims 20 and 25 depend from claim 19 and are therefore patentable over Hite for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

Summers

The Examiner has rejected claims 19, 20 and 25 under 35 U.S.C. § 102(b) as being anticipated by Summers et al. ("Hydroxamic Acid Inhibitors of 5-Lipoxygenase: Quantitative Structure-Activity Relationships", *Journal of Medical Chemistry*, Vol. 33, pp. 992-998 (1990)) ("Summers"). See Office Action at p. 5. Claims 20 and 25 are dependent on independent claim 19.

Summer describes the use of 5-lipoxygenase inhibitors as a "potential new approach" in the therapeutic intervention of asthma, arthritis and psoriasis. See p. 992, 1st paragraph. Summers does not describe a method of treating lung disease in a mammal that includes administering to the mammal a compound including an oxyamide linkage in an amount effective to inhibit sodium ion transport. See amended claim 19.

Accordingly, independent claim 19 is not anticipated by Summers. Claims 20 and 25 depend from claim 19 and are therefore patentable over Summers for at least the reasons described above. Applicants respectfully request reconsideration and withdrawal of this rejection.

Zusi

The Examiner has rejected claims 1-14, 19, 20 and 25 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,731,382 to Zusi et al. ("Zusi") in view of Egan et al.

("Modulation of Ion Transport in Cultured Rabbit Tracheal Epithelium by Lipoxygenase," *American Journal of Respiratory Cell and Molecular Biology*, Vol. 7, pp. 500-506 (1992)) ("Egan"). See Office Action at p. 5. Claims 2-14 are dependent on independent claim 1. Claims 20 and 25 are dependent on independent claim 19.

The Examiner contends that "Zusi discloses compounds of formula (I) and their activity as inhibitors of 5-lipoxygenase inhibitors. Zusi discloses ... the utility of these compounds in the treatment of asthma and COPD." See Office Action at p. 5. The Examiner further cites Egan as support to show "that inhibition of the lipoxygenase pathway inhibits sodium ion transport (absorption)" and alleges that "[t]he instantly claimed method for inhibiting sodium ion transport is therefore inherently anticipated by the methods of treatment of Zusi." See Office Action at p. 5. Applicants respectfully traverse this rejection.

Applicants have discovered a method of inhibiting sodium ion transport in an airway epithelial cell that includes contacting the cell with a compound including an oxyamide linkage in an amount effective to inhibit sodium ion transport. Applicants have further discovered a method of treating lung disease in a mammal that includes administering to the mammal a compound including an oxyamide linkage in an amount effective to inhibit sodium ion transport.

Zusi describes "relates to novel hydroxamic acid compounds which inhibit the enzyme, 5-lipoxygenase." See col. 1, lines 8-10. Zusi does not teach a method of inhibiting sodium ion transport in an airway epithelial cell that includes contacting the cell with a compound including an oxyamide linkage in an amount effective to inhibit sodium ion transport. Zusi further does not teach a method of treating lung disease in a mammal that includes administering to the mammal a compound including an oxyamide linkage in an amount effective to inhibit sodium ion transport.

Egan describes studies on the modulation of ion transport in freshly isolated rabbit tracheal epithelial cells using nordihydroguaiaretic acid (NDGA) which is described as "a general inhibitor of the lipoxygenase pathway." See Abstract on p. 500. Egan does not teach a method of inhibiting sodium ion transport in an airway epithelial cell that includes contacting the cell with a compound including an oxyamide linkage in an amount effective to inhibit sodium ion transport. Egan further does not teach a method of treating lung disease in a mammal that includes administering to the mammal a compound including an oxyamide linkage in an amount

effective to inhibit sodium ion transport. Applicants submit that nordihydroguaiaretic acid belongs to a different class of compounds altogether and therefore should not used as a secondary reference to demonstrate "the instantly claimed method for inhibiting sodium ion transport is inherently anticipated by methods of the treatment of Zusi." See Office Action at p. 5.

As such, independent claims 1 and 19 and dependent claims thereof are not anticipated by Zusi. Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims now pending are in condition for allowance.

Should any fees be required by the present Amendment, the Commissioner is hereby authorized to charge Deposit Account **19-4293**.

Respectfully submitted,

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